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**INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

Substitute for form 1449B/PTO

Complete if Known **Application Number** 10/057,726 **Filing Date** January 24, 2002 First Named Inventor Gary K. OWENS et al. Art Unit 1636 **Examiner Name** To Be Assigned

(use as many sheets as necessary)

Sheet Attorney Docket Number 021258-000200US of 1

	U.S. PATENT DOCUMENTS							
		Document Number						
Examiner	Cite No.1	Number Kind Code <sup>2</sup> (il known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			

FOREIGN PATENT DOCUMENTS								
Examiner Cite		Foreign Patent Document			Name of Patentee or	Pages, Columns, Lines,		
	No.'	Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>s</sup> (if known)	Publication Date MM-DD-YYYY	Applicant of Cited  Document	Where Relevant Passages or Relevant Figures Appear	Т6
_ <del>                                       </del>	1	PCT	WO 94/20629	A1	09-15-1994	Owens, G. K.	<del></del>	П
_0>	2	PCT	WO 99/36101	A1	07-22-1999	Bleadsdalo etal		

OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²		
B	3	LOFTUS, B. et al. "Genome duplications and other features in 12 Mb of DNA sequence from human chromosome 16p and 16q," <i>Genomics</i> 1999, pp. 295-308, Vol. 60.			

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

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STATEMENT BY APPLICANT	First Named Inventor	Owens, Gary K.	2 AUG 1 6 2007
	Art Unit	Unassigned	H

021258-000200US Attorney Docket Number **U.S. PATENT DOCUMENTS** Document Number Publication Date MM-DD-YYYY Name of Patentee or Applicant of Cited Document Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear Cite No.1 Number Kind Code<sup>2</sup> (if known) Examiner

Examiner Name

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Substitute for form 1449B/PTO Complete if Known **Application Number** 10/057,726 INFORMATION DISCLOSURE Filing Date January 24, 2002 STATEMENT BY APPLICANT **First Named Inventor** Owens, Gary K. Art Unit Unassigned

(use as many sheets as necessary) **Examiner Name** Unassigned Sheet of Attorney Docket Number 021258-000200US

	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS							
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X	AA	AIKAWA et al., "Human smooth Muscle Myosin Heavy Chain Isoforms as Molecular Markers for Vascular Development and Athersclerosis," <u>Circulation Research</u> , 73(6):1000-1012 (1993).						
	AB	AIKAWA et al., "Redifferentiation of Smooth Muscle Cells After Coronary Angioplasty Determined via Myosin Heavy chain Expression," Circulation, 96(1):82-90 (1997).						
	AC	BABIJ et al., "Tissue-specific and developmentally regulated alternative splicing of a visceral isoform of smooth muscle myosin heavy chain," Nuc. Acids Res., 21(6):1467-1471 (1993).						
	AD .	BABJI et al., "Differential expression of SM1 and SM2 myosin isoforms in cultured vascular smooth muscle," Am. J. Physiol., 262:C607-C613 (1991).						
	AE	BABJI et al., "Characterization of a mammalian smooth muscle myosin heavy-chain gene: Complete nucleotide and protein coding sequence and analysis of the 5' end of the gene," PNAS, 88:10676-10680 (1991).						
	ΛF	BABJI et al., "Myosin Heavy Chain Isoform diversity in Smooth Muscle is Produced by Differential RNA Processing," J. Mol. Biol., 210:673-679 (1989).						
	AG	BORRIONE et al., "Myosin heavy-chain isoforms in adult and developing rabbit vascular smooth muscle," <u>Eur. J. Biochem.</u> , 183:413-417 (1989).						
	АН	BOUVAGNET et al., "Multiple Positive and Negative 5' Regulatory elements control the Cell-Type-Specific expression of the Embryonic Skeletal Myosin Heavy-Chain Gene," Molecular and Cellular Biol., 7(12):4377-4389 (1987).						
	ΑI	CHAMLEY-CAMPBELL et al., "What Controls Smooth Muscle Phenotype," <u>Atherosclerosis</u> , 40:347-357 (1981).						
	AJ	FIRULLI et al., "Modular regulation of muscle gene transcription: a mechanism for muscle cell diversity," <u>Trends in Genetics</u> , 13(9):364-369 (1997).						
	AK	FISHER et al., "Developmental and Tissue Distribution of Expression of non Muscle and Smooth Muscle Isoforms of Myosin Light Chain Kinase," <u>Biochem. and Biophys. Res. Comm.</u> , 217(2):696-703 (1995).						
	AL	FRID et al., "Myosin Heavy-Chain Isoform Composition and distribution in Developing and Adult Human Aortic Smooth Muscle," J. Vaşc. Res., 30:279-292 (1993).						
	АМ	KALLMEIER et al., "A Novel Smooth Muscle-specific Enhancer Regulates Transcription of the Smooth Muscle Myosin Heavy Chain Gene in Vascular Smooth Muscle Cells," J. Biol. Chem., 270(52):30949-30957 (1995).						
l	AN	KATOH et al., "Identification of Functional Promoter Elements in the Rabbit Smooth Muscle Myosin Heavy Chain Gene," J. Biol. Chem., 269(48):30538-30545 (1994).						
DS	ΛО	KAWAMOTO et al., "Characterization of Myosin Heavy Chains in Cultured Aorta Smooth Muscle Cells," <u>J. Biol. Chem.</u> , 262(15):7282-7288 (1987).						

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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	Complete if Known		١
Application Number	10/057,726	OIPE	L
Filing Date	January 24, 2002	/	
First Named Inventor	Owens, Gary K.	Alic	17
Art Unit	Unassigned	HOD 1 6 2002	l
Examiner Name	Unassigned	2	4
Attorney Docket Number	021258-000200US	VA.	۶
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		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
$\mathcal{L}$	AP	KELLEY et al., "An Insert of Seven Amino Acids Confers Functional Differences between Smooth Muscle Myosins from the Intestines and Vasculature," J. Biol. Chem., 268(17):12848-12854 (1993).	
	AQ	KOCHER et al., "Cytoskeletal Features of Normal and Atheromatous Human Arterial Smooth Muscle Cells," <u>Human Pathology</u> , 17(9):875-880 (1986).	
	AR	KOCHER et al., "Phenotypic Features of Smooth Muscle Cells during the Evolution of Experimental Carotid Artery Intimal Thickening biochemical and Morphologic Studies," <u>Laboratory Invest.</u> , 65(4):459-470 (1991).	
	AS	HAMADA et al., "Distinct vascular and intestinal smooth muscle myosin heavy chain mRNAs are encoded by a single-copy gene in the chicken," <u>Biochem. Biophys. Res. Comm.</u> 170(1):53-58 (1990).	
	ΑT	MADSEN et al., "Smooth muscle-Specific Expression of the Smooth Muscle Myosin Heavy Chain Gene in Transgenic Mice Requires 5' -Flanking and First Intronic DNA Sequence," <u>Circulation Research</u> , 82:908-917 (1998).	
	AU	MADSEN et al., "Identification of a Positive CIS Element in the Rat Smooth Muscle Myosin Heavy Chain Promoter," Federation of American Societies of Experimental Biology Journal, 10(3):A343, abst. 1977 (1996).	
	ΑV	MADSEN et al., "Interaction of CArG Elements and a GC-rich Repressor Element in Transcriptional Regulation of the Smooth Muscle Myosin Heavy Chain Gene in Vascular Smooth Muscle Cells," J. Biol. Chem., 272(47):29842-29851 (1997).	
	AW	MADSEN et al., "Expression of the Smooth Muscle Myosin heavy Chain Gene Is Regulated by a Negative-acting GC-rich Element Located between Two Positive-acting Serum Response Factor-binding Elements," <u>J.</u> Biol. Chem., 272(10):6332-6340 (1997).	
	AX	MANABE et al., "CArG elements control smooth muscle subtype-specific expression of <i>smooth muscle myosin</i> in vivo," J. Clin. Invest., 107(7):823-834 (2001).	
	AY	MANABE et al., "The Smooth Muscle Myosin Heavy Chain Gene Exhibits Smooth Muscle Subtype-selective Modular Regulation in Vivo*," J. Biol. Chem., 276(42):39076-39087 (2001).	
	ΑZ	MIANO et al., "Smooth Muscle Myosin Heavy Chain Exclusively Marks the Smooth Muscle Lineage During Mouse Embryogenesis," Circulation Research, 75:803-812 (1994).	
	ВА	NAGAI et al., "Identification of Two Types of Smooth Muscle Myosin Heavy Chain Isoforms by cDNA Cloning and Immunoblot Analysis*," J. Biol. Chem., 264(17):9734-9737 (1989).	
	ВВ	OWENS, G.K., "Regulation of Differentiation of Vascular Smooth Muscle Cells," Physiological Reviews, 75(3):487-517 (1995).	
	ВС	REGAN et al., "Development of a Smooth Muscle-Targeted Cre Recombinase Mouse Reveals Novel Insights Regarding Smooth Muscle Myosin Heavy Chain Promoter Regulation," <u>Circ. Res.</u> , 87:363-369 (2000).	
<b>\$</b> 3	BD	REUSCH et al., "Mechanical Strain Increases Smooth Muscle and Decreases Nonmuscle Myosin Expression in Rat Vascular Smooth Muscle Cells," Circulation Research, 79:1046-1053 (1996).	

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known					
Application Number	10/057,726	7010			
Filing Date	January 24, 2002	7 9			
First Named Inventor	Owens, Gary K.	R AUG . C a			
Art Unit	Unassigned				
Examiner Name	Unassigned	The state of the s			
Attorney Docket Number	021258-000200US	W. C. W. C. W. C. W. C. W. C. W.			

OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS					
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DE BE		ROSS et al., "The pathogenesis of atherosclerosis: a perspective for the 1990s," Nature, 362:801-809 (1993).			
	BF	ROVNER et al., "Two different heavy chains are found in smooth muscle myosin," Am. J. Physiol., 250:C861-C870 (1986).			
	BG	ROVNER et al., "Expression of Smooth Muscle and Nonmuscle Myosin Heavy Chains in Cultured Vascular Smooth Muscle Cells*," J. Biol. Chem., 261(31):14740-14745 (1986).			
	вн	SARTORE et al., "Myosin Isoform Expression in Smooth Muscle Cells during Physiological and Pathological Vascular Remodeling," J. Vasc. Res., 31:61-81 (1994).			
	BI	SARTORE et al., "Myosin heavy-chain isoforms in human smooth muscle," <u>Eur. J. Biochem.</u> , 179:79-85 (1989).			
	BJ	SARTORELLI et al., "Muscle-Specific Gene Expression, A Comparison of Cardiac and Skeletal Muscle Transcription Strategies," <u>Circulation Research</u> , 72:925-931 (1993).			
	вк	SCHWARTZ et al., "Developmental Mechanisms Underlying Pathology of Arteries," Physiological Reviews, 70(4):1177-1209 (1990)			
	BL	WANG et al., "Expression of Smooth Muscle Myosin Isoforms in Urinary Bladder Smooth Muscle during Hypertrophy and Regression," <u>Laboratory Investigation</u> , 73(2):244-251 (1995).			
	ВМ	WATANABE et al., "Structure and Characterization of the 5' -Flanking Region of the Mouse Smooth Muscle Myosin Heavy Chain (SM 1/2) Gene," Circulation Research, 78:978-989 (1996).			
	BN	WHITE et al., "Identification of Promoter Elements involved in Cell-Specific Regulation of Rat Smooth Muscle Myosin Heavy Chain Gene Transcription*," J. Biol. Chem., 271(25):15008-15017 (1996).			
	во	WHITE et al., "Identification of a novel smooth muscle myosin heavy chain cDNA: isoform diversity in the S1 head region," Am. J. Physiol., 264:C1252-C1258 (1993).			
B	ВР	WILLS et al., "Tissue-specific expression of an anti-proliferative hybrid transgene from the human smooth muscle α-actin promoter supresses smooth muscle cell proliferation and neointima formation," Gene Therapy, 8:1847-1854 (2001).			

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